

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

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In re:

No. 3:06-MD-01760

AREDIA and ZOMETA
PRODUCTS LIABILITY LITIGATION
(MDL No. 01760)

JUDGE CAMPBELL
MAGISTRATE JUDGE BROWN

This Document Relates to: All Cases

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**PLAINTIFFS' STEERING COMMITTEE'S MOTION AND
SUPPORTING MEMORANDUM TO COMPEL DISCOVERY
AND FOR SANCTIONS AND ATTORNEY'S FEES FOR
VIOLATION OF THIS COURT'S DISCOVERY ORDERS**

Comes the Plaintiffs Steering Committee (hereinafter "the PSC"), pursuant to Rule 37, F.R.C.P., and moves the Court for entry of an order sanctioning Defendant Novartis Pharmaceuticals Corporation (hereinafter "Defendant" or "Novartis") for failure to obey an order to provide discovery, for attorney's fees incurred in connection with this motion, and to compel the discovery that has already been ordered by this Court. In support of this motion the PSC would show as follows:

1. On motion of the PSC in this matter, Novartis has already been ordered by this Court to provide the PSC with a "detailed" log explaining all redactions to documents produced in this litigation, and to refrain from marking as "confidential" documents which plainly cannot support any claim of confidentiality. Novartis has violated both of these orders by this Court, by:
 - (a) utterly failing to provide **any** explanation for the thousands of redactions on documents produced by Novartis; (b) by continuing to be grossly over-inclusive in marking documents as confidential.

2. On January 7, 2007, the PSC moved to compel Novartis to provide discovery in several different respects (DE 230). This motion was granted in part and denied in part in a detailed order entered herein on January 25, 2007 (DE 279). An additional order further addressing some of the issues raised in the PSC's motion to compel as well as other matters was entered herein on March 12, 2007 (DE 342).

2. Although the PSC believes that the Defendant has failed to comply with the referenced orders in several respects and anticipates the need for subsequent motions addressing Defendant's lack of compliance with those orders, this motion relates solely to Defendant's failure to comply with the Court's directives concerning redaction of documents and designation of documents as confidential. The PSC submits that Novartis has abused the discovery process and violated the Court's discovery orders by providing an incomplete and inadequate redaction log, excessively redacting documents, and designating non-confidential documents as confidential.

3. The PSC further submits that it is entitled to an order directing Novartis to produce unredacted documents that are not designated as confidential as a sanction for Defendant's failure to comply with the Court's discovery orders and an order awarding attorney's fees incurred in connection with this motion.

DISCUSSION

A. The Applicable Law

Rule 37(b)(2), F.R.C.P., provides as follows: "If a party ... fails to obey an order to provide or permit discovery ... or if a party fails to obey an order entered under Rule 26(f), the court in which the action is pending may make such orders in regard to the failure as are just.... ." The rule goes on to state, "... the court shall require the party failing to obey the order or the

attorney advising that party or both to pay the reasonable expenses, including attorney's fees, caused by the failure, unless the court finds that the failure was substantially justified or that other circumstances make an award of expenses unjust." Novartis has blatantly disregarded the Magistrate Judge's orders pertaining to redaction of documents and designation of documents as confidential. Consequently, Novartis should be ordered to produce all redacted documents without any redactions, other than redactions which may be required by express statutory or regulatory provisions along with a redaction log identifying the specific statutory or regulatory provision upon which each remaining redaction is based, and without confidentiality designation. Further, the PSC should be awarded its expenses in connection with this motion, including reasonable attorney's fees.

B. The Applicable Orders

In ruling upon the PSC's previous motion in which the PSC complained that Novartis had produced thousands of documents containing improper redactions, the Magistrate Judge stated as follows:

As to the redactions, while Rule 26(b)(5) does not expressly require a log to support the redactions, the Magistrate Judge believes that the Plaintiffs are entitled to some explanation as to why something is redacted. There is a big difference between a portion of the document being marked out as irrelevant and a portion of the document being marked out as confidential. The Plaintiffs have no way of knowing whether the redaction is due to some claim of statutory or regulatory confidentiality or immateriality when it is simply blocked out without explanation.

* * *

In short, the Magistrate Judge does not believe that the Defendant can universally designate everything as confidential and, at the same time, redact a portion of the material as confidential. If documents are designated as confidential, the Defendant does not need to withhold them as confidential unless there is, perhaps, a specific regulatory or statutory basis for doing so.

... The Magistrate Judge trusts that the parties will fully comply with the spirit of such provisions.

See DE 279, pp 4-5.

In a subsequent lengthy telephone conference with the Magistrate Judge in this matter on March 8, 2007, the PSC again raised the issue of the Defendant's improper redaction of documents. In ruling upon the PSC's objections in that conference, the Magistrate Judge's order stated:

A good deal of time was spent discussing documents that had previously been redacted on the grounds of relevancy. The Defendant points out that in a single document they may discuss relevant matters concerning the drugs Aredia and Zometa as well as discussion of marketing plans for other drugs unrelated to this litigation. They point out that this other material would be irrelevant to this case and they are entitled to withhold it. The Plaintiffs, on the other hand, point out that when they receive a document with names marked out of the address line or pages marked out, they have no way of knowing what was redacted or why it was redacted. Accordingly, the Magistrate Judge expects a detailed explanation of why material has been redacted from a document. The Magistrate Judge would further strongly recommend that the Defendant use its blackout pen sparingly as there is a protective order in this case.

* * *

The parties are advised, however, that if the Plaintiffs submit a sample of documents to the Magistrate Judge and the Magistrate Judge finds that they have been improperly redacted, the Magistrate Judge will sweep broadly from that sample, absent some specific need for redaction. Therefore, the Magistrate Judge once again trusts that the Defendant will be very judicious in using the blackout marker and will provide detailed explanations for redacted material.

DE 342, pp. 3-4 (emphasis in original).

C. Defendant's Misconduct

1. Redactions/Redaction Log

The so-called redaction “logs” proffered by Novartis pursuant to this order is anything but “a detailed explanation of why material has been redacted from a document.” As part of Novartis’s document production in May, 2007, Novartis provided in electronic format nothing more than three text files which were identified solely by the file name and ***which contained only a list of Bates numbers and no other information.*** There is ***no explanation at all for the redactions.*** It is ***merely a list of bates numbers*** referencing documents containing redactions.

One of the text files is named “Redactions_not_responsive_info_20070514.txt.” This file is a 1,632 KB file containing literally hundreds of pages of Bates numbers and no other information. This file identifies over ***112,000 redacted documents*** with ***no explanation whatsoever for any of the redactions.*** A sample of the material contained in this text file, showing that it is nothing but a list of bates numbers, is attached hereto as Exhibit 1.

A second text file is named “Redactions_other_personal_info_20070514.txt.” This file is an 11 KB file that consists of 14 pages of Bates numbers ***and no other information.*** A hard copy of this file is attached hereto as Exhibit 2.

The third such file is a text file entitled “Redactions_FDA_20070514.txt.” This file is a 1,389 KB file which also contains hundreds of pages of Bates numbers ***with no further explanation.*** A sample of the information contained in this file is attached hereto as Exhibit 3.

On June 8, 2007, the PSC wrote Defendant’s counsel concerning missing Bates numbers and missing coding data in documents produced by Novartis pursuant to the Magistrate Judge’s order of March 12, 2007, and a bad computer disk provided by Novartis. A copy of the PSC’s letter is attached hereto as Exhibit 4. On June 13, 2007, counsel for Novartis partially responded to the PSC’s letter of June 8, 2007. A copy of Novartis’s counsel’s letter is attached hereto as

Exhibit 5. On June 20, 2007, the PSC wrote counsel for Novartis in follow-up to its letter of June 8, 2007. A copy of this letter is attached hereto as Exhibit 6.

In this letter, the PSC raised the issue of Defendant's compliance with the Court's orders concerning a redaction log:

Which brings me to the "logs" produced with the production. In addition to a privilege log, Novartis produced three text files which contained only a list of bates numbers and no other information. These files were named:

- Redactions_not_responsive_info_20070514.txt
- Redactions_other_personal_info_20070514.txt
- Redactions_FDA_20070514.txt

No information or explanation whatsoever for the redactions is included. This is in violation of the MDL Court's March 12, 2007 Order, which states: "Accordingly, the Magistrate Judge expects a detailed explanation of why material has been redacted from a document." (March 12, 2007 Order, p. 4) (emphasis in original).

See letter of Bart Valad to Katharine Latimer, dated June 20, 2007 (Exhibit 6 hereto).

By letter dated June 28, 2007, counsel for the Defendant responded to the PSC's letter of June 20, 2007, concerning the redaction log as follows:

As to your questions about the redaction logs, I disagree that we are "in violation" of the Court's order; indeed, we have provided the logs as directed. To further assist you with the logs, "Redactions not responsive" encompasses redactions of information about Novartis drugs other than Zometa® or Aredia® from otherwise responsive documents; the category "Redactions other personal" encompasses redactions of non-responsive information (such as credit card numbers, social security numbers, and other personal information) from otherwise responsive documents; "Redactions FDA" encompasses the FDA-mandated redaction of patient and adverse event reporter identifier information from otherwise responsive documents.

See letter of Katharine R. Latimer, dated June 28, 2007 (Exhibit 7 hereto).

Nothing the PSC can say would better illustrate Defendant's abuse of the discovery process and total disregard of this Court's order than Novartis's counsel's letter of June 28, 2007.

The Magistrate Judge emphasized in his order that he expected a detailed explanation of why material was redacted from a document. Novartis has provided no explanation for its redactions, much less a detailed explanation. Defendant's counsel's assertion that it has "provided the logs as directed" ignores reality. Novartis is simply determined to avoid production of as many documents as possible which may contain relevant and useful information for the Plaintiffs. The Court can understand how Novartis has wielded its "blackout marker" by reference to examples of some of the specific documents redacted by Novartis.

Attached hereto as Exhibit 8 (filed under seal) is an internal document of Novartis with the title and most of the content removed from the document. Of course, since the redaction "logs" contain only a bates number and absolutely no explanation whatsoever as to why this document is redacted, Plaintiffs cannot assess the legitimacy of the redactions.

Attached hereto as Exhibit 9 (filed under seal) is an excerpt of an article written by Dr. John W. Hellstein, one of the *Plaintiffs' experts*, which has been redacted by Defendant and identified by Defendant in its so-called FDA redaction log. It is beyond contemplation how this document, which is a paper written and published by one of the *Plaintiffs' experts* could conceivably contain information that Novartis is entitled to redact, but Novartis has done so. Novartis has, on this document, redacted the name of the institution where Dr. Hellstein works, the University of Iowa. It appears, when Novartis's erroneous redactions are viewed in context, that Novartis has used some keyword search algorithm to perform automated redactions, and any institution whose name also happens to be the reporter of an adverse event is automatically redacted in other places throughout the production (some are later fixed by hand, some are not).

Attached as Exhibit 10 (filed under seal) is a document that appears on its face to be a letter sent to "All Associates world-wide." Despite its obvious wide distribution without

apparent concern for confidentiality or sensitivity of its contents, large portions of the document are redacted, again without any explanation because the logs contain no explanation whatsoever.

Attached hereto as Exhibit 11 (filed under seal) is a document containing e-mail correspondence which appears to be between employees of the Defendant and a Zometa IIRP investigator. This document is identified by Novartis's so-called FDA redaction log. For inexplicable reasons, however, Novartis has redacted Ms. Landesberg's e-mail address, the institution at which she works, or some other identifying information concerning Ms. Landesberg. There is simply no basis for redaction of this information by Novartis.

Despite Novartis's protestations concerning its detailed examination of these documents and redaction of documents only for specified reasons, Exhibits 9 and 11 clearly imply that Novartis is simply using an editing program to locate and redact specific words in the documents it produces without regard to the context in which those words are used or the nature of the document in which the words are contained. There is simply no other decipherable explanation for Defendant's redaction of the names of institutions set forth in a published article such as Exhibit 9 or the name of the institution at which an otherwise identified Zometa IIRP investigator is employed.

Further, Plaintiffs have seen redacted documents that do not appear in any log. See Exhibit 12 filed under seal, which appears to be a published article with an inexplicable redaction at the top of the first page. Why Novartis would redact this article (and include the confidentiality legend) is a mystery. This document is not included in any log documenting the redaction.¹

¹ Attached hereto as Exhibit 13 (filed under seal) is an internal document of Novartis entitled "Osteonecrosis and Bisphosphonate Therapy Communication Strategy" wherein both

2. Confidentiality Designation

Novartis has also disregarded the Magistrate Judge's orders with respect to designation of documents as confidential. The Protective and Confidentiality Order (DE 100) previously entered herein strictly limits the Plaintiffs' use of documents designated by Novartis as confidential and, among other things, requires that any such documents filed with the Court be filed under seal. The protective order provides that any party may designate a document as confidential material by stamping it "Confidential" or "Subject to Protective Order." See DE 100 at p. 2.

In the PSC's Motion to Compel (DE 230), the PSC complained that Novartis had designated every document it has produced in the case to that point as confidential. The legend utilized by Novartis to designate the documents as confidential stated, "Produced pursuant to Protective Order entered in case 3:06-md-1760 (MD Tenn.)." See *e.g.* Exhibit 1 to PSC's initial Motion to Compel, DE 231 (filed under seal). In the proceedings addressing that motion, Novartis conceded that every document produced by it to that point had been designated as confidential through use of that legend. See DE 279 at p. 3.

The gist of the PSC's Motion to Compel with respect to this issue was that in many instances, the Defendant had no legitimate basis to designate documents it had produced as confidential. The PSC pointed out that many documents such as newspaper articles, magazine

osteonecrosis of the jaw and the drugs at issue in this action are discussed. Novartis has obviously redacted any words from this document which might suggest a causal relationship between this disease and these drugs. Although this document appears in the privilege log, this appears to be a highly questionable basis for a redaction, and suggests that future motion practice regarding the very voluminous privilege log is likely.

articles and other publicly available documents had been designated by Novartis as confidential. In ruling upon the PSC's motion with respect to this issue, the Magistrate Judge stopped short of requiring Novartis to remove the confidentiality legend from documents previously produced², but with respect to documents produced in the future, stated as follows:

The Magistrate Judge believes that the Defendant may not simply designate every document produced as confidential. The Plaintiffs have pointed out that the Defendant has used this blanket use of protective order to designate newspaper and magazine articles as confidential. Had this been raised with the Magistrate Judge at an earlier time, he could have given earlier guidance. It appears to the Magistrate Judge that if Defendant is reviewing documents for relevancy, privilege, and confidentiality redactions, it is not an undue burden for the Defendant to determine whether a produced document should be designated as confidential. The Defendant shall make reasonable efforts to designate as confidential only those documents which, in fact, it contends should be maintained as confidential under the protective order.

DE 279 at p. 4.

Despite the Magistrate Judge's ruling, Novartis has continued to designate virtually every document it produces as confidential. In the May 15, 2007 production, Novartis produced 5,295,747 pages of documents, including 1,408,825 pages of documents that had never been produced before. In these more than 5 million pages of documents, every document Plaintiffs have seen so far includes the confidentiality legend. On July 2, 2007, Novartis produced 1,465,579, and Plaintiffs have seen only a handful of documents that do not contain the legend.

In fact, attached hereto as Exhibit 14 (filed under seal) is an article appearing in a published journal which discusses osteonecrosis of the jaw associated with the use of

² With respect to documents already produced, the Magistrate Judge did direct the parties to confer concerning any requests the PSC may have for removal of the legend from any particular document and for Novartis to address the PSC's request in good faith when no basis for the designation existed. The examples cited herein contain only documents produced for the first time after the Court's order directing Novartis not to abuse the confidentiality legend.

bisphosphonates and designated by Novartis as produced by Novartis with the confidentially legend after entry of the Magistrate Judge's order in January, 2007. Attached hereto as Exhibit 15 (filed under seal) is an article published in the *Journal of the American Dental Association* discussing the care of patients with bisphosphonate associated osteonecrosis, which has also been designated as confidential by Novartis in its production made since entry of the Magistrate Judge's order. Attached hereto as Exhibit 16 (filed under seal) are copies of letters to the editor published in *The Journal of Oral and Maxillofacial Surgeons* which has been designated by Novartis as confidential in its document production since entry of the Magistrate Judge's order.

There is no conceivable basis for Novartis to have designated these documents as confidential. Novartis has simply disregarded the Magistrate Judge's ruling. It was Novartis's burden to comply with this Court's order and designate as confidential only those documents for which a claim of confidentiality can be made. While representing to the Court that it is doing a time-consuming, thorough, thoughtful review of every document produced in this case, plainly it is doing something else altogether.

CONCLUSION

Novartis has been ordered to provide a "detailed" redaction log explaining why it redacted documents. Novartis has also been ordered to use its blackout marker sparingly and only to redact documents on which redaction is legally appropriate. Novartis has refused to comply with this order. The Magistrate Judge has ruled that Novartis may not simply designate every document produced as confidential. Novartis has been ordered to make reasonable efforts to designate as confidential only those documents which should appropriately be maintained as confidential. Novartis has likewise refused to comply with this aspect of the Court's order. In short, ***despite having twenty-two months time to produce documents in response to Plaintiffs'***

request for production, Novartis has disregarded the Magistrate Judge's orders, abused the discovery process, and increased the cost of discovery to the PSC. Accordingly, Novartis should be ordered to produce unredacted documents that are not designated as confidential as a sanction for Defendant's failure to comply with the Court's discovery orders, and the Court should award the PSC its expenses incurred in connection with this motion, including reasonable attorney's fees.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have on this 20th day of July, 2007, served a true and correct copy of the foregoing pleading by operation of the Court's Electronic Case Filing System to counsel of record in this case, including:

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